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May 17, 2010

VIA ECF AND FEDEX

The Honorable Mark Falk, U.S.M.J. United States District Court U.S.P.O. & Courthouse Bldg., Room 457 One Federal Square Newark, New Jersey 07102

Re:

Sepracor Inc. v. Teva Pharmaceuticals USA, Inc., et al.

Civil Action No. 09-1302 (DMC)(MF)

Dear Judge Falk:

This firm, together with Paul, Hastings, Janofsky & Walker LLP, represents Plaintiff Sepracor Inc. in the above-captioned matter. Pursuant to Your Honor's May 10, 2010 Order, we write to respond to Defendants' 12-page April 27th letter (D.I. 269) regarding the production of suriclone-related documents.

At the outset, it should be noted that the parties long ago reached agreement on the production of suriclone-related documents in *Sepracor's* possession, *and Sepracor has produced such documents*. Accordingly, Defendants cannot seriously claim that Sepracor should be precluded from relying on suriclone-related information (and at a minimum publicly available documents relating to that compound), as Sepracor has upheld its discovery obligations with respect to documents in its possession, custody, and control.

Further, with respect to the issue raised in the Court's May 10th Order (whether Sepracor has the "legal right" to obtain suriclone-related discovery from Sanofi), Defendants appear to argue that Sepracor can somehow force Sanofi — a third-party French company with no financial interest in the outcome of this case — to produce documents in this U.S. litigation. The agreement assigning the eszopiclone invention from Sanofi to Sepracor (the "Agreement"), however, does *not* obligate Sanofi to produce such documents, and Sanofi has already expressly informed Defendants, Sepracor, and this Court that it will not produce them. Sepracor cannot compel a foreign third party to produce documents that the third party will not agree to produce. Moreover, as Sepracor's counsel explained during the March 15th hearing, Sanofi's internal development work relating to suriclone is irrelevant to what the publicly available, prior-art literature disclosed to those of ordinary skill in the art with respect to the claimed invention. For these reasons and the reasons set forth below, Defendants' motion to compel should be denied.

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The Honorable Mark Falk, U.S.M.J. May 17, 2010 Page 2

A. Relevant Background

Defendants' April 27th letter attempts to create the impression that Sepracor is planning to broadly rely upon unproduced information relating to the compound suriclone in this case. But as Sepracor's counsel made clear at the March 15th hearing (D.I. 250 at 20-21), Sepracor intends to rely upon only certain prior-art literature concerning that compound that would have suggested to those of ordinary skill in the art — to the extent it would have ever occurred to them to even attempt to separate the enantiomers of zopiclone — that the active enantiomer of zopiclone was the "R-" form of zopiclone, not the "S-" form of zopiclone that is covered by the patents-in-suit. Suriclone has no relevance to this litigation beyond this issue of how those of skill in the art would interpret these prior-art references *based upon publicly available information*. Nor have Defendants contended otherwise in their submissions to the Court addressing this dispute. Further, this publicly available information is as readily available to Defendants as it is to Sepracor.

Nevertheless, Defendants have broadly demanded discovery relating to the development of suriclone, a chemical entity that is entirely distinct from the compound at issue in this case. With respect to document requests directed to Sepracor, Defendants and Sepracor have resolved any remaining disputes with respect to suriclone-related discovery in Sepracor's possession. Thus, the present motion is *not* directed to documents in Sepracor's possession, as these documents have already been produced by Sepracor.

Instead, the present motion is directed to discovery requested from third party Sanofi. In this regard, Defendants first sent a letter to Sanofi and Sepracor on June 24, 2009, seeking 19 categories of documents, one of which (category "R") was directed to "all articles, publications, presentations, and white papers (to the extent they are in the possession or under the control of RPR/Sanofi) of each of the individuals identified in Section II related to RPR/Sanofi work on Ssuriclone, R-suriclone, and/or suriclone." (Ex. 1, Defs.' 6/24/09 Ltr., at 4, 6.) In response, Sepracor specifically noted that category R was *outside the scope of Sanofi's obligations under the Agreement*. (Ex. 2, Sepracor's 6/30/09 Ltr., at 1.) After additional correspondence between the parties confirming that Defendants' June 24th letter constituted the "complete scope of requested discovery" (*see* Ex. 3, Sepracor's 7/17/09 Ltr., at 1; Ex. 4, Defs.' 7/21/09 Ltr.), Sanofi agreed to produce documents in response to virtually all of Defendants' document requests. With respect to suriclone, however, Sanofi made clear that

[a]s to category R, it relates to suriclone and its enantiomers, which are different chemical entities than eszopiclone. As such, we believe suriclone is *not covered by the . . . Agreement. Moreover*, the request is overly broad and *encompasses publicly available information*. As such, Sanofi will not collect such documents.

(Ex. 5, Sanofi's 7/31/09 Ltr., at 2 (emphasis supplied).)

The Honorable Mark Falk, U.S.M.J. May 17, 2010 Page 3

Before making its objection, Sanofi's counsel's warned Defendants that, "given [Sanofi]'s non-party status, they wish to avoid the unnecessary burden of making multiple collections of documents." (Ex. 6, Sanofi's 7/7/09 Ltr.) At the same time, Defendants represented that their "goal" was "to expeditiously identify and resolve any potential disputes regarding [the] information and documents" sought from Sanofi. (Ex. 4, Defs.' 7/21/09 Ltr.) Nevertheless, Defendants did not challenge Sanofi's objection to producing suriclone-related documents based on the plain language of the Agreement. Instead, in a letter sent two weeks later that "follow[ed]up" on Sanofi's July 31st letter, Defendants did not even mention the issue of suriclone discovery. (Ex. 7, Defs.' 8/13/09 Ltr.)

Not until October 15, 2009 — two-and-a-half months after Sanofi's objection — did Defendants again raise the issue of obtaining suriclone discovery from Sanofi. After noting Sanofi's clear objection to this discovery (particularly given the timing of Defendants' request), Sepracor agreed to meet and confer with Defendants in an effort to avoid the need for Court intervention. During that meet and confer, Defendants agreed that their "request for discovery relating to 'Sanofi's suriclone activities' . . . is overbroad and would encompass, for example, documents having no relevance to this litigation." (Ex. 8, 12/22/09 E-mail to Defs. from Sepracor.) Sepracor also made clear that, although it "has no ability to commit third-party Sanofi" to any discovery, it was "willing to approach Sanofi regarding a narrowed, reasonable scope of suriclone-related documents." (Id.)

Instead of making such a proposal, Defendants *actually expanded* the scope of documents requested in its initial June 24th letter — the same letter that Defendants represented to be the "complete scope of requested discovery" from Sanofi. Worse yet, the additional requests were directed to a broad scope of documents having nothing to do with the merits of this case, including:

[I]nternal RPR/Sanofi documents which describe:

- i) efficacy or activity or S-isomer suriclone or R-isomer of suriclone with respect to the benzodiazepine receptor;
- ii) interaction of S-isomer of suriclone, R-isomer of suriclone, or racemic suriclone with the benzodiazepine receptor; or
- iii) resolution of S-isomer of suriclone or R-isomer of suriclone from racemic suriclone.
- (Ex. 9, Defs.' 12/22/09 Ltr., at 2.) **By definition**, such "internal RPR/Sanofi documents" that are not available to the public cannot inform one of ordinary skill as to the *likely* active enantiomer of suriclone *before* that compound is separated which the parties do not dispute is the only relevance of the suriclone literature to this case. Instead, such documents would indicate only

The Honorable Mark Falk, U.S.M.J. May 17, 2010 Page 4

what the active enantiomer *is* once racemic suriclone has been separated into its enantiomers. Accordingly, this information is irrelevant.

Sepracor subsequently requested (again) a proposal that actually narrowed, rather than expanded, Defendants' original request for suriclone-related documents from Sanofi. (See Ex. 10, Sepracor's 1/6/10 Ltr., at 2) Defendants ignored this proposal and, despite Sepracor's efforts to reach a compromise, submitted its long-winded April 27th letter to the Court.

B. Sepracor Does Not Have Control of the Requested Discovery

The party seeking production of documents bears the burden of establishing the producing party's control over the documents. *Camden Iron and Metal, Inc. v. Marubeni America Corp.*, 138 F.R.D. 438, 441 (D.N.J. 1991). Here, Defendants' own arguments conclusively prove that Sepracor does not have control of the requested documents. First, according to Defendants, Sepracor asked Sanofi to produce the suriclone-related discovery set forth in Defendants' June 24th letter. (*See D.I.* 269, 4/27/10 Ltr., at 4-5 ("Sepracor wrote to Sanofi on July 27, 2009, and requested that Sanofi produce responsive non-privileged documents, specifically excepting racemic zopiclone but not suriclone.").) Sanofi refused to provide that discovery as outside the Agreement. (*See Ex. 5*, Sanofi's 7/31/09 Ltr., at 2.) Accordingly, ordering Sepracor to do anything with respect to Sanofi's suriclone-related documents would be futile.¹

Recognizing that the Agreement does not cover suriclone-related documents, Defendants argue that, "[e]ven were there no provision in the agreement between Sepracor and Sanofi requiring Sanofi to produce the requested documents and witnesses, such an obligation exists under an assignment such as the one here." (D.I. 269, 4/27/10 Ltr., at 10.) But the cases relied upon by Defendants do not even remotely bear upon the facts at hand. Instead, those cases involve situations where a party was compelled to produce documents *in the possession of a corporate parent, affiliate, or successor. See Afros S.P.A. v. Krauss-Maffei Corp.*, 113 F.R.D. 127, 130-31 (D. Del. 1986) (ordering "wholly owned subsidiary" to produce documents in possession of parent corporation and noting that "[t]he 'nature of the relationship' between the party over whom the court has jurisdiction and the non-party with possession of the documents will determine whether a motion to compel discovery will be granted"); *In re Global Power Equipment Group, Inc.*, 418 B.R. 833, 842-85 (Bankr. D. Del. 2009) (finding "closely

As noted above, Defendants also request in the alternative to "preclude Sepracor from relying on arguments related to suriclone." (D.I. 269, 4/27/10 Ltr., at 12.) This argument is nonsensical because, as Defendants acknowledge, Sepracor has agreed to provide various suriclone-related discovery in its possession, and the parties do not dispute the scope of that production. Further, Defendants do not and cannot claim that Sepracor intends to rely upon any documents that Sanofi has not produced. At a minimum, Sepracor should be entitled to rely upon publicly available documents relating to suriclone.

Case 2:09-cv-01302-DMC -MF Document 277 Filed 05/17/10 Page 5 of 37

The Honorable Mark Falk, U.S.M.J. May 17, 2010 Page 5

intertwined sister corporations" to have control over each other's documents for purposes of the litigation); *Bank of New York v. Meridien Biao Bank*, 171 F.R.D. 135, 147-48 (S.D.N.Y. 1997) (finding documents of corporation that "would be receiving an assignment of [the party's] rights in this case" to be within the control of the party); *In re NTL, Inc. Securities Litig.*, 244 F.R.D. 179, 195-97 (S.D.N.Y. 2007) (ordering that documents of company emerging out of bankruptcy proceeding were discoverable through second company emerging from same bankruptcy proceeding).

Here, Sepracor and Sanofi have no corporate relationship whatsoever, and Defendants do not contend otherwise. In such circumstances, courts deny the existence of "control" under Rule 34. See, e.g., Novartis Pharms. Corp. v. Eon Labs Mfg., Inc., 206 F.R.D. 392, 395 (D. Del. 2002) (denying motion to compel documents in possession of third party pursuant to license agreement because the "respective business operations of each entity [were not] so intertwined as to render meaningless their separate corporate identities"); see also Inline Connection Corp. v. AOL Time Warner, Inc., 2006 U.S. Dist. LEXIS 72724, at *9 (D. Del. Oct. 5, 2006) ("In the case of two independent corporate entities . . . production of documents would only occur when the respective business operations of each independent entity are 'so intertwined as to render meaningless' their distinct corporate identities.").

C. Sanofi Correctly Interpreted the Agreement to Exclude Suriclone-Related Discovery

The only potential basis for Sanofi to be required to produce the discovery at issue is through the Agreement. But as Sanofi has made clear on numerous occasions (and Sepracor agrees), such discovery is plainly not covered by the "RPR Application or the invention it claims" language in that agreement.

Defendants contend that because *Sepracor* relied upon suriclone-related *prior art* during prosecution of one of the patents-in-suit in 2008, this somehow required Sanofi to produce broad discovery relating to suriclone, including *internal documents*, pursuant to its 1999 agreement. But even assuming that Sepracor's unilateral actions — nearly a decade after its agreement with Sanofi — could commit third-party Sanofi to produce foreign documents in a U.S. litigation, Defendants' overbroad interpretation of the "pertain[s] to the RPR application" language would eviscerate the "or the invention it claims" language. In other words, because "the invention" of the "RPR application" (*i.e.*, eszopiclone) was of course necessarily discussed during the prosecution of the patents-in-suit, Defendants' interpretation of the Agreement would render one of the two categories of documents superfluous. Such a plainly improper interpretation should be rejected in favor of the natural reading of the language, to which both parties to the contract at issue subscribe and which gives effect to all of its language, namely: the "RPR application" refers to the prosecution files of the patents-in-suit, and "the invention it claims" refers to eszopiclone. There is no dispute between the parties regarding this discovery.

Case 2:09-cv-01302-DMC -MF Document 277 Filed 05/17/10 Page 6 of 37

The Honorable Mark Falk, U.S.M.J. May 17, 2010
Page 6

D. Defendants' Hague Request Should Be Denied

As explained above, the overbroad discovery that Defendants now seek via the Hague Convention is irrelevant to the issues in this case. And to the extent Defendants' Hague requests seek publicly available information, Defendants can just as easily obtain this information as third parties. Sepracor therefore joins in the objections to these requests set forth in Sanofi's letters to the Court addressing this issue. (D.I. 268, 273.)

E. Conclusion

Sepracor has already provided certain suriclone-related information to Defendants, and it cannot compel Sanofi, a third party not under its control, to provide more. Further, it is improper to preclude Sepracor from relying on the suriclone-related information it has already produced because Defendants seek irrelevant additional information from third-party Sanofi. Accordingly, Defendants' motion to compel should be denied.

Charles M. Lizza

cc: All Counsel (via e-mail)

Case 2:09-cv-01302-DMC -MF Document 277 Filed 05/17/10 Page 8 of 37

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June 24, 2009

Originals By First Class Mail Confirmation By Email

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Re: Sepracor Inc. v. Teva Pharmaceuticals USA, Inc., et al. Civ. No. 2:09-cv-01302 (DMC) (MF) (D.N.J.) -- eszopiclone

Gentlemen:

I write this letter on behalf of all Defendants named¹ in the above identified action, which is an ANDA litigation involving the drug eszopiclone sold by Sepracor Inc. ("Sepracor") under the trade name LUNESTA[®]. In particular, this letter is directed to obtaining discovery, particularly deposition testimony and documentation, from Rhone Poulenc Rorer ("RPR"), now Sanofi-Aventis ("Sanofi"), concerning development work related to the drug eszopiclone, the patent prosecution process (including the interference between RPR and Sepracor), and the transfer of patent rights and other assets from RPR to Sepracor. Defendants understand that RPR/Sanofi is being represented by Fitzpatrick, Cella, Harper & Scinto and provide the following background for RPR/Sanofi.

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The named Defendants are Teva Pharmaceuticals USA, Inc., Wockhardt Ltd., Wockhardt USA, LLC, Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc., Roxane Laboratories, Inc., Cobalt Laboratories Inc., Cobalt Pharmaceuticals Inc., Glenmark Generics Inc., USA, Glenmark Generics, Ltd., Glenmark Pharmaceuticals, Ltd., Orchid Healthcare (a Division of Orchid Chemicals & Pharmaceuticals, Ltd., Orgenus Pharma Inc., Lupin Pharmaceuticals, Inc., Lupin Ltd., Sun Pharma Global Inc., Sun Pharmaceutical Industries Inc., Sun Pharmaceutical Industries Ltd., Alphapharm Pty. Ltd., and Mylan, Inc. (collectively, "Defendants").

Joseph M. O'Malley, Esq. Brian V. Slater, Esq. June 24, 2009 Page 2

I. Background

On March 20, 2009, Plaintiff Sepracor brought this action against Defendants, alleging infringement of U.S. Patent Nos. 6,319,926 ("the '926 patent"), 6,444,673 ("the '673 patent"), 6,864,257 ("the '257 patent"), and 7,381,724 ("the '724 patent") (collectively, "the patents-insuit").

Though Sepracor is the present assignee of the patents-in-suit, Defendants are aware that RPR was responsible for, *inter alia*, its development of the claimed subject-matter ("eszopiclone") of the patents-in-suit; the filing of a French patent application to which the patents-in-suit claim priority; and the prosecution of the first seven U.S. patent applications in the family of applications leading to the patents-in-suit. Defendants are further aware that in 1999, RPR assigned, *inter alia*, its eszopiclone patent rights and know-how to Sepracor. We understand that as part of the assignment, RPR/Sanofi agreed to cooperate for purposes of discovery in this matter.

On May 14, 2009, Magistrate Judge Falk ordered a scheduling conference to be held on June 19, 2009. As required by the order, the parties met and conferred regarding discovery issues prior to the scheduling conference. At the parties' meet and confer, Defendants raised the issue of obtaining discovery – both documents and depositions – from RPR/Sanofi regarding eszopiclone. Prior to the scheduling conference, we understand that Sepracor contacted and spoke with RPR/Sanofi. Sepracor subsequently responded to Defendants² and explained that RPR/Sanofi, "with respect to discovery of relevant [S]anofi witnesses and documents in this litigation ... intends to fully comply with its obligations to Sepracor under the 1999 License and Assignment Agreement." Sepracor's response also indicated that Sanofi is willing to produce "(i) non-privileged company files that pertain to the RPR Application or the invention it claims; and (ii) former RPR employees currently employed by Sanofi having personal knowledge concerning the RPR Application or the invention it claims." The response further explained that no "subpoena or other formal process (served via the Hague Convention or otherwise) would be required in connection with the above-specified scope of discovery."

At the June 19, 2009 scheduling conference before Magistrate Judge Falk, the Defendants raised the issue of obtaining discovery from RPR/Sanofi. Defendants told the Court they were trying to work out the issues with Sepracor and asked the Court to set a date in July for the parties to update the Court on the progress on this discovery and identify any issues remaining. Defendants indicated they would identify questions they had for Sepracor and RPR/Sanofi to facilitate discovery from RPR/Sanofi in this litigation. The Court has calendared a conference for July 23, 2009 at 10:00 a.m. in Magistrate Falk's courtroom. In addition, the Court and Sepracor's counsel invited RPR/Sanofi's counsel to participate in the conference on July 23.

See June 18, 2000 email from Joseph M. O'Malley (attached).

Joseph M. O'Malley, Esq. Brian V. Slater, Esq. June 24, 2009 Page 3

The Defendants set forth below some initial questions and requests regarding the discovery anticipated from RPR/Sanofi.

II. <u>Defendants' Discovery Requests From RPR/Sanofi – RPR/Sanofi Persons</u> Knowledgeable About Eszopiclone

Defendants seek discovery from at least the following individuals who were, upon information and belief, involved in the development of eszopiclone and/or involved in the prosecution of the applications (including the interference between RPR and Sepracor) that led to the issuance of the patents-in-suit:

A. Claude Cotrel

Claude Cotrel is a named inventor of the patents-in-suit. Defendants submit that this witness may have discoverable information relevant to, among other things, the subject matter and prosecution of the patents-in-suit.

B. Gerard Roussel

Gerald Roussel is a named inventor of the patents-in-suit. Upon information and belief, Roussel was an employee of RPR. He prepared and submitted one or more declarations in U.S. Patent Application No. 08/342,794. Defendants submit that this witness may have discoverable information relevant to, among other things, the subject matter and prosecution of the patents-in-suit.

C. Jean-Charles Blanchard

Upon information and belief, Jean-Charles Blanchard was an employee of RPR. He prepared and submitted one or more declarations in U.S. Patent Application Nos. 07/821,662; 08/034,199; 08/342,794; and 08/493,946. Defendants submit that this witness may have discoverable information relevant to, among other things, the subject matter and prosecution of the patents-in-suit.

D. Odile Piot

Upon information and belief, Odile Piot was an employee of RPR. Piot prepared and submitted one or more declarations in U.S. Patent Application No. 08/493,946. Defendants submit that this witness may have discoverable information relevant to, among other things, the subject matter and prosecution of the patents-in-suit.

E. Ian Martin

Upon information and belief, Ian Martin was a member of the Department of Pharmacology at the University of Alberta in Edmonton, CA. Martin prepared and submitted one or more declarations in U.S. Patent Application No. 08/493,946. Defendants submit that this witness may have discoverable

Joseph M. O'Malley, Esq. Brian V. Slater, Esq. June 24, 2009 Page 4

information relevant to, among other things, the subject matter and prosecution of the patents-in-suit.

F. Marc Stanilas Bonnefoi

Upon information and belief, Marc Stanilas Bonnefoi was an employee of RPR. He prepared and submitted one or more declarations in U.S. Patent Application No. 08/493,946. Defendants submit that this witness may have discoverable information relevant to, among other things, the subject matter and prosecution of the patents-in-suit.

G. Adam Doble

Upon information and belief, Adam Doble was an employee of RPR. He prepared and submitted one or more declarations in U.S. Patent No. 6,319,926. Defendants submit that this witness may have discoverable information relevant to, among other things, the subject matter and prosecution of the patents-in-suit.

H. M. Martinet, G.J. Sanderink, P. Gires, P. Chevalier, V. Piguet, J. Gailliot

These individuals are listed as authors of Martinez *et al.*, "Stereoselective biotransformation of suriclone enantiomers and active metabolite in vitro," Pharmacocinetique: de la recherché a la clinique. Ed. J. bries, G. Paris. John Libbey eurotext, 225-230 (1992). According to the first page of the reference (attached), these individuals were all employed by RPR.

I. Other RPR/Sanofi individuals involved in the development of eszopiclone and prosecution of the applications leading to the patents in suit

There were undoubtedly other RPR/Sanofi individuals, unknown to Defendants, who were involved in (a) the development of eszopiclone; (b) prosecution (including the interference between RPR and Sepracor) of the applications leading to the patents in suit; and/or (c) the transfer of the eszopiclone technology and/or patent rights from RPR to Sepracor. Defendants request the identity of those individuals now to facilitate the receipt of discovery from RPR/Sanofi.

J. Corporate Witness

Defendants would also like to know whether RPR/Sanofi's counsel will accept a 30(b)(6) deposition subpoena and provide a corporate witness.

For each of the above individuals, please provide the following information:

- 1. Is he/she currently an employee of RPR/Sanofi? If the individual is a former employee, what is his/her current address, phone number and/or email address?
- 2. Will RPR/Sanofi's counsel be representing the individual, and if so will they accept service of process directed to that person?

Joseph M. O'Malley, Esq. Brian V. Slater, Esq. June 24, 2009 Page 5

- 3. Will RPR/Sanofi make the individual available for deposition? If so, will RPR/Sanofi produce the individual in the U.S.? We assume that all depositions of all individuals will be U.S. style in form. Please confirm.
- 4. Is the individual fluent in (*i.e.*, speak and understand) English or will he/she require a translator at his/her deposition?
- 5. Was the individual involved in the transfer of the eszopiclone technology and/or eszopiclone patent rights from RPR to Sepracor?

III. <u>Defendants' Discovery Requests From RPR/Sanofi – Documents Relating To Eszopiclone</u>

The Defendants also seek a description, and the production, of all documents, both electronic and hard copy, in the possession, custody, or control of RPR/Sanofi, related to the prosecution (including the interference between RPR and Sepracor) of the applications that led to the issuance of the patents-in-suit and the claimed subject-matter in the patents-in-suit, including but not limited to documents concerning:

- **A.** all employment agreements for individuals identified in Section II;
- **B.** all assignments of the applications underlying the patents-in-suit;
- C. RPR's decision to develop a single enantiomer of zopiclone, including any documents concerning any consideration given to the development or Rzopiclone;
- **D.** the development of eszopiclone;
- **E.** analysis and testing of eszopiclone, R-zopiclone, and zopiclone (*e.g.*, optical rotation measurements, enantiomeric purity measurements, etc.)
- **F.** the efficacy and toxicity of eszopiclone, R-zopiclone, and zopiclone;
- **G.** the preparation and filing of U.S. regulatory documents regarding eszopiclone;
- **H.** RPR/Sanofi's decision to assign its patent rights to eszopiclone;
- I. communications with Sepracor regarding eszopiclone, including correspondence with Sepracor related to the enforcement of any of the patents-in-suit;
- **J.** the prosecution of the applications leading to the patents-in-suit;
- **K.** the prosecution of any U.S. patent applications or foreign patent applications directed to R-zopiclone;
- L. the prosecution of the foreign counterparts to the patents-in-suit;
- M. all Know How and Improvements as defined by the Sepracor/(RPR/Sanofi) September 30, 1999 and July 2, 2004 License Agreements;

Joseph M. O'Malley, Esq. Brian V. Slater, Esq. June 24, 2009 Page 6

- N. evidence of alleged unexpected properties or advantages eszopiclone has relative to zopiclone;
- **O.** strategy for marketing eszopiclone against zopiclone;
- **P.** statements made by any consultants/experts who were retained by RPR/Sanofi for the purpose of evaluating eszopiclone and/or R-zopiclone;
- Q. all articles, publications, presentations, and white papers (to the extent they are in the possession or under the control of RPR/Sanofi) of each of the individuals identified in Section II related in any way to eszopiclone, R-zopiclone, and/or zopiclone;
- **R.** all articles, publications, presentations, and white papers (to the extent they are in the possession or under the control of RPR/Sanofi) of each of the individuals identified in Section II related to RPR/Sanofi work on S-suriclone, R-suriclone, and/or suriclone; and
- S. the curriculum vitae of each of the individuals identified in Section II.

With respect to the above requested documents, Defendants request the following information:

- 1. How and when will these documents be produced to Defendants?
- 2. Will RPR/Sanofi's counsel accept a subpoena for the above requested documents?
- 3. Are the documents in French?
- 4. Since RPR began development of eszopiclone, what has been the document retention policy of RPR/Sanofi?
- 5. Were any of the above documents once in the possession of RPR but subsequently transferred to Sepracor when the eszopiclone technology and/or eszopiclone patent rights were transferred/assigned from RPR to Sepracor? If so, which documents were transferred?

IV. <u>Defendants' Discovery Requests From RPR/Sanofi – Samples</u>

Defendants further request the following information regarding zopiclone, eszopiclone, and R-zopiclone samples ("zopiclone samples") which were manufactured by RPR:

- **A.** a list of the zopiclone samples (by sample number and any other identifier);
- **B.** policies and procedures at RPR/Sanofi related to the retention of the zopiclone samples;
- **C.** the identity of custodians of the zopiclone samples;

Case 2:09-cv-01302-DMC -MF Document 277 Filed 05/17/10 Page 14 of 37

GOODWIN PROCTER

Joseph M. O'Malley, Esq. Brian V. Slater, Esq. June 24, 2009 Page 7

- **D.** analysis of the zopiclone samples (*e.g.*, optical rotation measurements, enantiomeric purity measurements, etc.); and
- **E.** a list of the names and dates for persons to whom or entities to which RPR/Sanofi sent samples of the zopiclone samples.

Please explain whether any of the above samples and/or documentation regarding zopiclone samples were once in the possession of RPR but subsequently transferred to Sepracor when the eszopiclone technology and/or eszopiclone patent rights were transferred/assigned from RPR to Sepracor. In addition, please identify any samples or documentation so transferred.

Please let the Defendants know at your earliest convenience whether RPR/Sanofi will comply with and/or respond to the above requests. Please also let Defendants know if you need any clarification regarding the abovementioned discovery issues. Lastly, please let Defendants know whether RPR/Sanofi counsel will attend the conference scheduled for July 23 at 10:00 a.m.

Very truly yours,
Marker & H

Marta E. Gross

cc: (By email only) All Defendants' Counsel

Paul Hastings

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June 30, 2009

72603.00007

VIA E-MAIL

Mr. Brian V. Slater, Esq. Fitzpatrick, Cella, Harper & Scinto 30 Rockefeller Plaza New York, NY 10112

Re:

Sepracor Inc. v. Teva Pharmaceuticals USA, Inc., et al.

Civ. Action No. 09-1302 (DMC)(MF)

Dear Brian:

This is in response to your June 25, 2009 letter regarding discovery of Aventis Pharma SA.

In accordance with the September 30, 1999 License and Assignment Agreement between Sepracor Inc. and Rhône-Poulenc Rorer SA, Sepracor hereby formally requests from Aventis company files that pertain to the RPR Application or the invention it claims.

With respect to the requests for specific documents set forth in Marta Gross's June 24th letter on behalf of all defendants in the above-captioned action, without knowledge of the documents Aventis has in its possession, it is difficult to know how the above category of documents relate to Defendants' detailed requests. We note, however, that the requests relating broadly to racemic zopiclone, such as Requests III.E-F, III.P-R, and IV.A-E in Defendants' letter, appear to go well beyond "Company files that pertain to the RPR Application or the invention it claims," particularly given my understanding that RPR (now, Aventis) developed and sells racemic zopiclone in Europe. But we defer to you for guidance on such requests.

Paul *Hastings*

Mr. Brian V. Slater, Esq. June 30, 2009 Page 2

Please do not hesitate to contact me if you would like to discuss the above.

Sincerely,

Joseph M. O'Malley, Jr.

of PAUL, HASTINGS, JANOFSKY & WALKER LLP

cc. Defendants' counsel

LEGAL_US_E # 84253967.1

Paul Hastings

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July 17, 2009

72603.00007

VIA E-MAIL

Marta E. Gross, Esq. Goodwin Procter LLP 620 Eighth Avenue New York, NY 10018

Re: Sepracor Inc. v. Teva Pharmaceuticals USA, Inc., et al., No. 09-1302 (DMC)(MF)

Dear Marta:

This is in response to your July 16, 2009 letter.

We had been communicating with Sanofi, and were prepared to ask them to produce at least a significant subset of the categories of documents requested in your June 24th letter, when we received Defendants' July 10, 2009 Requests for Production of Documents and Things. Those requests were surprising in that, *inter alia*, they could be read as seeking documents in the possession of non-party Sanofi, in addition to Sepracor. (See Definition No. 1 of "Sepracor" referring to "documents from Rhône-Poulenc Rorer, now Sanofi-Aventis.")

Sanofi has indicated to us on several occasions that, prior to searching for and producing any documents, it wants to know the complete scope of the requested discovery. Your July 16th letter appears to state that the June 24th requests comprise the universe of documents that will be requested of Sanofi, and that the July 10th requests for production were sent as merely a "courtesy" to Sanofi. Please confirm that this is the case. If Defendants' intent in serving the July 10th document requests was to expand the scope of discovery requested of Sanofi, however, then we will respond in due course to those requests instead of the requests set forth in your June 24th letter.

We look forward to hearing from you.

Marta E. Gross, Esq. July 17, 2009 Page 2

Very truly yours,

of PAUL, HASTINGS, JANOFSKY & WALKER LLP

cc: Defendants' counsel

Marta E. Gross 212.459.7499 mgross@goodwinprocter.com Goodwin Procter LLP Counselors at Law The New York Times Building 620 Eighth Avenue New York, NY 10018 T: 212.813.8800 F: 212.355.3333

July 21, 2009

VIA E-MAIL

Joseph M. O'Malley, Esq. Paul Hastings Janofsky & Walker LLP 75 E. 55th Street New York, NY 10022

Re: Sepracor Inc. v. Teva Pharmaceuticals USA, Inc. *et al.*Civ. No. 2:09-cv-01302 (DMC) (MF) (D.N.J.) – eszopiclone

Dear Joe:

This responds to your July 17, 2009 letter.

My July 16, 2009 letter specifically referred to both my June 24, 2009 letter and defendants' July 10, 2009 document requests. The July 10 document requests encompass the same universe of documents as the June 24 letter, albeit in more detail. That being said, if you interpret the July 10 document requests as encompassing RPR/Sanofi-Aventis documents that were not included in the June 24 request, defendants desire production of those documents as well.

In the end, our goal is to receive the requested information and documents (from RPR/Sanofi-Aventis and/or Sepracor) as soon as possible, and to expeditiously identify and resolve any potential disputes regarding such information and documents.

Very truly yours,

Marta E. Gross

cc: Brian V. Slater, Esq. (via e-mail) Defendants' Counsel (via e-mail)

The July 10 document requests used the definition of Sepracor quoted in your letter because it is our understanding that pursuant to the agreement between RPR/Sanofi-Aventis and Sepracor, Sepracor has control over the requested documents and information in the possession of RPR/Sanof-Aventis.

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July 31, 2009

Via Email

Joseph M. O'Malley, Esq Paul, Hastings, Janofsky & Walker Park Avenue Tower 75 E. 55th Street New York, NY 10022

Re:

Sepracor Inc. v. Teva Pharmaceuticals USA, Inc., et al.

Civ. No. 2:09-cv-01302 (DMC) (MF) (D.N.J.)

Dear Joe:

This will respond to your July 27, 2009 letter formally requesting Sanofi to collect and provide to Sepracor non-privileged documents falling within 19 categories (III. A through S) set forth in Ms. Gross' June 24, 2009 letter with the proviso that Sepracor is not requesting Sanofi to collect documents relating to racemic zopiclone (except to the extent they compare racemic zopiclone to R(-) or S(+) zopiclone).

We understand from your letter that Sepracor construes its requests as falling within the scope of Article 6 of the September 30, 1999 License and Assignment Agreement between Sepracor and Rhone-Poulenc Rorer SA (now Aventis Pharma SA) ("1999 Agreement"). We also understand from your letter and prior discussions that Sepracor agrees to reimburse Sanofi for the outside attorney fees/expenses, scanning, copying, translator and other vendor costs associated with the collection, review and production of such documents subject to the provisions of Article 5.5. If our understandings are incorrect, please let us know.

Assuming our understandings are correct, Sanofi agrees to make a reasonable search for and provide to Sepracor one copy of non-privileged, non-work product documents that Sepracor has requested, except category R (discussed below), with the following caveats:

(I) Sanofi objects to disclosing personal information that it is prohibited from disclosing by data privacy laws or regulations;

Joseph M. O'Malley, Esq July 31, 2009 Page 2

- (II) Sanofi objects to producing marketing or financial documents;
- (III) Sanofi objects to searching its libraries for scientific literature, patents, prior art or other publicly-available information. Sanofi will, however, produce such documents to the extent they are requested and are found based on a reasonable search of the files of individuals identified in Section II. A through D, F and G of Ms. Gross' letter;
- (IV) Sanofi is willing to provide a privilege log for documents requested except for internal foreign prosecution documents. We will, however, provide requested foreign prosecution documents sent to or received from any national public Patent Office or the EPO, as well as prior art found in those prosecution files;
- (V) As to electronic discovery, we understand from Ms. Gross' July 16, 2009 letter that she intends her requests to cover electronic discovery. You have not made clear whether Sepracor wishes Sanofi to make a search for electronic documents. To the extent Sepracor does so request, we will need your request to be more specific in terms of which custodians files you wish us to search for electronic documents, how the electronic files should be produced and which search terms you propose. In any event, Sanofi objects to searching any back-up tapes or historical legacy data. We await your clarification on electronic discovery.
- (VI) As previously advised, Sanofi will require the entry of a suitable protective order protecting Sanofi's confidential information before Sanofi will produce any of the documents to Sepracor. Please let us have a draft protective order at your earliest convenience.

As to category R, it relates to suriclone and its enantiomers, which are different chemical entities than eszopiclone. As such, we believe suriclone is not covered by the 1999 Agreement. Moreover, the request is overly broad and encompasses publicly available information. As such, Sanofi will not collect such documents.

If you believe that any of these caveats or objections will interfere with Sepracor's rights under the 1999 Agreement, please give us a detailed explanation of Sepracor's position with regard to each such objection so Sanofi has a chance to consider it fully.

As I will be in China next week, if you wish to discuss any of these matters, we can do so when I return.

Very truly yours,

Brian V. Slater

Defendants' counsel (via e-mail)

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July 7, 2009

Via Email

Joseph M. O'Malley, Esq Paul Hastings Park Avenue Tower 75 E. 55th Street First Floor New York, NY 10022

Re: Sepracor Inc. v. Teva Pharmaceuticals USA, Inc., et al

Civ. No. 2:09-cv-01302 (DMC) (MF) (D.N.J.)

Dear Joe:

This responds to your June 30, 2009 letter.

As we have said, our client is committed to providing the information set forth in the contract between our respective clients. Based on prior discussions, we have begun identifying repositories of documents within our client's files. While your letter states that your client now formally requests documents under the contract, your letter does not specify which categories of documents Sepracor is requesting under the terms of the contract. As we also have explained in our prior discussions, given our client's non-party status, they wish to avoid the unnecessary burden of making multiple collections of documents. To that end, we have requested that Sepracor work out with the Defendants the categories of documents (including electronic documents, if any) Sepracor seeks from our client pursuant to the contract.

We, therefore, await a list of all categories of documents Sepracor is requesting our client to collect under the contract, which reflects the result of Sepracor's discussions with Defendants.

very truly yours

Brian V Clater

Case 2:09-cv-01302-DMC -MF Document 277 Filed 05/17/10 Page 29 of 37

GOODWIN PROCTER

Marta E. Gross 212.459.7499 mgross@goodwinprocter.com Goodwin Procter LLP Counselors at Law The New York Times Building 620 Eighth Avenue New York, NY 10018 T: 212.813.8800 F: 212.355.3333

August 13, 2009

VIA E-MAIL

Joseph M. O'Malley, Esq.
Paul Hastings, Janofsky

& Walker LLP

75 E. 55th Street

New York, NY 10022

Brian V. Slater., Esq
Fitzpatrick, Cell, Harper

& Scinto

30 Rockefeller Plaza
New York, NY 10112

Re: Sepracor Inc. v. Teva Pharmaceuticals USA, Inc. *et al.*Civ. No. 2:09-cv-01302 (DMC) (MF) (D.N.J.) – eszopiclone

Gentlemen:

This letter follows-up on the July 31, 2009 letter from Mr. Brian Slater.

The defendants have some follow-up questions about Mr. Slater's letter. For example, (1) what are the French privacy laws/regulations and what, if any, documents are being withheld on the basis of such privacy laws/regulations; and (2) who are the custodians whose files are being searched. We would also like to discuss the objections relating to the protective order and electronic discovery. We believe these questions can be addressed more efficiently in a telecon between the parties and Mr. Slater rather than letter writing.

We understand that Mr. Slater may be travelling in China now or in the near future. If Mr. Slater would propose time(s) for a telecon that would work for him, we could then schedule with the parties.

Very truly yours,

Mada & K

Marta E. Gross

cc: Defendants' Counsel (via e-mail)

Adamo, Tina M.

From: Dittmann, Eric W.

Sent: Tuesday, December 22, 2009 9:54 AM

To: 'epergament@kgplaw.com'; 'mgilman@kgplaw.com'; 'abc@saiber.com'

Cc: 'clizza@saul.com'; Panda, Jason K.

Subject: Lunesta Meet and Confer

Dear Ed.

I write to memorialize our meet and confer held yesterday regarding the suriclone-related documents Defendants seek from third-party Sanofi. During the meet and confer, you agreed with me that the request for discovery relating to "Sanofi's suriclone activities" set forth in your October 15, 2009 letter is overbroad and would encompass, for example, documents having no relevance to this litigation. You responded that a letter previously sent by another defendant set forth the more narrow scope of documents that Defendants actually seek, but were unable to identify that letter during our call. You indicated that you would identify the letter by e-mail after the call, but we have not yet heard from you.

As I stated during the meet and confer, Sepracor remains willing to approach Sanofi regarding a narrowed, reasonable scope of suriclone-related documents. Of course, Sepracor has no ability to commit third-party Sanofi one way or the other, but would be happy to discuss any such proposal with Sanofi in the interest of potentially avoiding a dispute before the Court.

If I have inaccurately summarized any portion of our call, please let me know. I am also available to discuss by telephone today and tomorrow if you wish.

Regards, Eric

KAPLAN GILMAN & PERGAMENT LLP

COUNSELORS AT LAW

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EDWARD D. PERGAMENT, PARTNER
NJ AND NY BARS, REG. PATENT ATTORNEY
epergament@kgplaw.com

December 22, 2009

VIA ELECTRONIC MAIL

Eric W. Dittmann, Esq. Paul, Hastings, Janofsky & Walker LLP 75 East 55th Street, 1st Floor New York, NY 10022

Re: Sepracor v. Teva et al.-Eszopiclone

Dear Eric:

This is in response to your e-mail today and further to our meet and confer yesterday, December 21, regarding Sanofi's suriclone documents.

As the initial matter, Defendants' requests for suriclone discovery always were and remain specific. I attach the June 24 letter from Marta Gross to Joe O'Malley and Brian Slater for your immediate reference. This letter, which I referenced on the call yesterday, was written on behalf of all Defendants including Glenmark. It specifically requested information about Messrs. Martinet et al., authors of the article entitled "Stereoselective Biotransformation of Suriclone Enantiomers and Active Metabolite In Vitro." At page 4, Section II.H. It also specifically requested "all articles, publications, presentations, and white papers (to the extent they are in possession or under the control of RPR/Sanofi) of each of the individuals identified in Section II related to RPR/Sanofi work on S-suriclone, R-suriclone, and/or suriclone." At page 6, section III.R. Defendants' Requests For Documents included Request 205 directed broadly to suriclone and Request 206 directed specifically to "all documents and things comparing any element, aspect or attribute of suriclone with any element, aspect or attribute of zopiclone, eszopiclone, or R-zopiclone." Per Brian Slater's letter of July 31, Sanofi refused to produce any suriclone-related documents or to provide any information regarding the identified individuals. I attach a copy of the follow-up October 1 letter from Anthony Fitzpatrick to Brian Slater, on behalf of all Defendants including Glenmark, which again specifically requested information about Messrs. Martinet et al. On October 5, Sanofi flatly refused to provide any suriclone discovery. It was only then that I wrote my October 15, 2009 letter, which responded to Sanofi's general refusal to provide suriclone discovery. Any assertion that Glenmark's requests for suriclone discovery were overly broad is not in accordance with the facts.

I understand that Sepracor will now consider making a demand to Sanofi for suriclonerelated discovery if a sufficiently narrow discovery request can be formulated.

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During prosecution of the '724 patent, Sepracor alleged that certain suriclone information is relevant to patentability of s-zopiclone. Glenmark does not currently take a position with respect to the <u>weight</u> of such suriclone-related information. However, Glenmark is entitled to discovery on any issue for which suriclone information <u>may</u> be alleged by anyone as potentially relevant to patentability of s-zopiclone. *Cf. Hickman v. Taylor*, 329 U.S. 495, 506-07, 67 S.Ct. 385, 91 L.Ed. 451 (1947). Specifically, Glenmark seeks the following specific suriclone-related information from Sanofi:

- a) whereabouts of Messrs. M. Martinet, G.J. Sanderink, P. Gires, P. Chevalier, V. Piguet, J. Gailliot, and any other individuals employed by RPR/Sanofi who may have information on the biological activity or toxicity of S-isomer of suriclone or R-isomer of suriclone; Glenmark also seeks access to those of these individuals who are still employed by Sanofi-Aventis;
- b) all articles, publications, presentations, white papers in possession of RPR/Sanofi that discuss biological activity or toxicity of S-isomer or R-isomer of suriclone; and
- c) only those internal RPR/Sanofi documents which describe
- i) efficacy or activity of S-isomer of suriclone or R-isomer of suriclone with respect to the benzodiazepine receptor;
- ii) interaction of S-isomer of suriclone, R-isomer of suriclone, or racemic suriclone with the benzodiazepine receptor; or
- iii) resolution of S-isomer of suriclone or R-isomer of suriclone from racemic suriclone.

Please let me know by December 30 whether Sepracor is prepared to make a formal request for this discovery from Sanofi under the 1999 Agreement. If we do not hear from you on or before December 30, Glenmark will write to the Court on or before January 6, 2010 with the intention to address this issue with Judge Falk at the January 12 conference.

Very truly yours,

KAPLAN GILMAN & PERGAMENT LLP

Edward D. Pergament

c: All Counsel of Record (via email) Brian Slater, Esq. (via email)

Paul Hastings

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January 6, 2010

72603.00007

VIA E-MAIL

Edward D. Pergament, Esq. Kaplan Gilman & Pergament LLP 1480 Route 9 North, Suite 204 Woodbridge, NJ 07095

Re: Sepracor Inc. v. Teva Pharms. USA, Inc., et al., No. 09-1302 (DMC)(MF)

Dear Ed:

This is in response to your December 22, 2009 letter regarding Glenmark's request for documents and witnesses from Sanofi relating to suriclone.

As a preliminary matter, you cite Marta Gross's June 24th letter in support of Glenmark's request. As I pointed out in my November 4th letter, however, Defendants waived their request for suriclone-related discovery by failing to timely contest Sanofi's objection to that discovery in Brian Slater's July 31st letter. Indeed, Sanofi's counsel informed Defendants as early as July 7th that, "given our client's non-party status, they wish[ed] to avoid the unnecessary burden of making multiple collections of documents." (7/7/09 Letter from Brian Slater.) Defendants understood this fact, representing that their "goal" was "to expeditiously identify and resolve any potential disputes regarding [the] information and documents" sought from Sanofi. (7/21/09 Letter from Marta Gross.) Yet in a letter purporting to "follow[]up" on Mr. Slater's July 31st letter objecting to suriclone-related discovery as outside the scope of the Sepracor-Sanofi Agreement, Ms. Gross did not in any way challenge that objection. (See 8/13/09 Letter from Marta Gross; see also 9/23/09 Letter from Marta Gross (failing to contest Sanofi's refusal to provide suriclone-related information requested in Section II.H of Defendants' June 24th letter).)

Instead, Defendants waited until October 1st — more than two months after Sanofi's objection — to address the issue of suriclone discovery from Sanofi. (See 10/1/09 Letter from Anthony Fitzpatrick.) And even that letter focused only on the information "requested in Section II(H) of the defendants' June 24th letter," which concerned "RPR/Sanofi Persons Knowledgeable About Eszopiclone." (Id. at 2-3.) After Sanofi once again reiterated its objection to providing suriclone-related discovery in an October 5th letter from Brian Slater, your October 15th letter on behalf of Glenmark broadly requested "document discovery . . . concerning Sanofi's suriclone activities" — which was the first reference by any defendant to suriclone-related documents since the original June

Paul Hastings

Edward D. Pergament, Esq. January 6, 2010 Page 2

24th request for documents from Sanofi. During our December 21st meet and confer, you agreed that this request was overbroad.

We also discussed during that meet and confer the possibility that — even though Sepracor has no ability to commit third-party Sanofi to providing any discovery — Sepracor could approach Sanofi again to the extent Glenmark was willing to request a narrowed, reasonable scope of suriclone-related documents. Instead of narrowing Defendants' previous requests, however, you have merely repeated them and added a new category directed to "internal RPR/Sanofi documents." This does not advance the meetand-confer process.²

Although Sepracor again has no ability to commit third-party Sanofi to any discovery, Sepracor remains willing to approach Sanofi regarding a reasonable scope of suriclone-related documents. Glenmark's continued attempts to expand the scope of discovery, however, make this process difficult. Please let us know if Glenmark is willing to make such a proposal in an attempt to avoid a dispute before the Court. We are available to meet and confer to the extent you believe this could be helpful.

Sincerely,

Eric W. Dittmann

for PAUL, HASTINGS, JANOFSKY & WALKER LLP

EWD

As I explained during our meet and confer, we disagree with the assertion in your December 15th letter that Sepracor has "control" over Sanofi's suriclone-related documents. We also note that the cases cited in your letter are inapposite to the facts at hand.

Moreover, my November 4th letter explained why such a request is (in addition to being untimely) irrelevant. To date, Glenmark has responded only that "private" documents "may be relevant." (12/15/09 Letter from Ed Pergament at 1.) That Defendants did not include this category of documents in their June 24th letter — which they represented as encompassing the universe of discovery sought from Sanofi — confirms that it is not relevant to any claim or defense in this action.